REMARKS

The invention relates in part to assay devices that utilize mass transport by laminar flow of a sample through the layers of the device. Because laminar flow overcomes limitations in sensitivity caused by diffusion boundary formation as an analyte binds to a surface, the devices of the present invention can provide advantageous capture efficiencies.

Claims 1-12, 18-34, and 36-50 are pending in the instant application. Claims 1-6, 18, 19, and 23 are amended herein. The amended claims are fully supported by the specification, and do not introduce new matter or require a new search. The amendments simply clarify the claimed invention using preferring terminology, and are not intended to further limit the claim, and should not be taken to do so.

Notwithstanding the foregoing, Applicants expressly reserve the right to pursue subject matter no longer claimed in the instant application in one or more applications which may claim priority hereto. Applicants respectfully request reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non Art-Related Remarks

35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1-12, 18-34, and 36-50 under 35 U.S.C. § 112, second paragraph, contending that these claims are allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

With regard to claims 39-50, Applicants respectfully request clarification of the rejection, as the instant rejection is based on language that is not present in these claims. With respect to the remaining claims, Applicants respectfully traverse this rejection.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). See also *Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the

specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added).

The examiner first contends that the skilled artisan could not understand the phrase "through layers of the device" in the context of laminar flow, because laminar flow allegedly occurs only parallel to a surface, and flow away from or towards a surface cannot be laminar flow. The Examiner cites U.S. Patent Nos. 4,685,534 ("the '534 patent"); and 6,096,068 ("the '068 patent") in support of this contention.

In contrast to the Examiner's contention, however, while laminar flow can be viewed for the sake of simplicity as flow along a flat plane, laminar flow need not be parallel to a flat surface. For example, the '534 patent states that "a particular type of laminar flow" may occur "around a stationary body or through a stationary conduit." *See, e.g.*, '534 patent, column 9, lines 52-60. The skilled artisan understands that laminar flow "around a stationary body" cannot be parallel to a flat plane, and but must "bend" around surfaces of the stationary body that are not coincident with a single plane. This type of laminar flow can be seen, for example, when fluid flows past particles in a chromatographic matrix, in a type of flow known as "streamline flow." *See, e.g.*, Giddings, *Unified Separation Science*, John Wiley & Sons, Inc., 1991, pp. 62, 74, and 75, provided herewith by Applicants for the convenience of the Examiner.

Considering, for example, a curved surface feature on a macroscopically planar surface, the direction of flow at a particular position on the curved feature need not be parallel to the planar surface; nonetheless, the flow can remain laminar across both the surface feature and the planar surface. This description of laminar flow is fully consistent with the description of laminar flow provided in the instant specification, *e.g.*, on page 3, line 21, through page 4, line 8, and in the instant claims. Thus, in a device comprising the supports of the instant claims, the skilled artisan will understand that flow in the instantly claimed devices may be both across and/or through the various layers, and yet still be laminar flow.

Therefore, because those skilled in the art are reasonably apprised of the scope of the invention, Applicants respectfully submit that the claims meet the standards of 35 U.S.C. § 112, and request that the Examiner withdraw the rejection.

The Examiner also contends that claims 1-12, 18-22, and 36-50 are unclear with regard to the phrase "through the layers," and claims 23-24 are unclear with regard to the phrase "said layers," as it is allegedly unclear as to which layers the claims refer. Applicants respectfully submit that the foregoing amendments to the claims render these rejections moot.

35 U.S.C. § 102

The Examiner has rejected claims 18, 19, and 23 under 35 U.S.C. § 102(b) as allegedly being anticipated by Brecht *et al.*, Anal. Chim. Acta 311: 289-299 (1999). This rejection, however, is based on the Examiner's flawed rejection under 35 U.S.C. § 112, second paragraph, discussed above. Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejection.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,
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Dated: June 29, 2001

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Appendix A: Marked-up claims, indicating amendments.

1. (Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a support containing channels[,];

an optically functional layer positioned on said support [such that said optically functional layer and said support allow for laminar flow of said sample through layers of said device,];

an attachment layer positioned on said optically functional layer[,]; and

an analyte specific receptive layer positioned on said attachment layer,

wherein sample flow through said layers of said device is laminar flow.

2. (Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a support containing channels[,];

an optically functional layer positioned on said support [such that said optically functional layer and said support allow for laminar flow of said sample through layers of said device,]; and

an attachment layer positioned on said optically functional layer,

wherein sample flow through said layers of said device is laminar flow.

3. (Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support[,];

an optically functional layer comprising discrete, optically functional particles embedded in said support[, such that said optically functional layer and said support allow for laminar flow of said sample through layers of said device,];

an attachment layer positioned on said particles[,]; and

an analyte specific receptive layer positioned on said attachment layer,

wherein sample flow through said layers of said device is laminar flow.

4. (Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support[,];

an optically functional layer comprising discrete, optically functional particles embedded in said support [such that said optically functional layer and said support allow for laminar flow of said sample through layers of said device,]; and

an attachment layer positioned on said particles,

wherein sample flow through said layers of said device is laminar flow.

5. (Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support[,];

an optically functional layer containing channels positioned on said support [such that said optically functional layer and said support allow for laminar flow of said sample through layers of said device,];

an attachment layer positioned on said optically functional layer[,]; and

an analyte specific receptive layer positioned on said attachment layer,

wherein sample flow through said layers of said device is laminar flow.

6. (Amended) An optical assay device for the detection of an analyte of interest in a sample comprising:

a porous support[,];

an optically functional layer containing channels positioned on said support[, such that said optically functional layer and said support allow for laminar flow of said sample through layers of said device,]; and

an attachment layer positioned on said optically functional layer,

wherein sample flow through said layers of said device is laminar flow.

18. (Twice amended) Method for constructing an optical assay device with laminar flow properties, comprising the steps of:

providing a support[,];

providing an optically functional layer on said support [such that said optically functional layer and said support allow for laminar flow of a sample through or through and across layers of said device,];

providing an attachment layer on said optically functional layer[,]; and

providing an analyte specific receptive layer on said optically functional layer, wherein said support and said layers are configured and arranged to provide laminar flow through or through and across said layers of said device.

19. (Twice amended) Method for constructing an optical assay device with laminar flow properties, comprising the steps of:

providing a support[,];

providing an optically functional layer on said support [such that said optically functional layer and said support allow for laminar flow of a sample through or through and across layers of said device,]; and

providing an attachment layer on said optically functional layer, wherein said support and said layers are configured and arranged to provide laminar flow through or through and across said layers of said device.

23. (Amended) A composition comprising a support and an optically functional layer [which is useful for promoting] configured and arranged to provide laminar flow of sample through said [layers] optically functional layer.